



UNITED STATES PATENT AND TRADEMARK OFFICE

SEP 18 2007

Commissioner for Patents  
United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

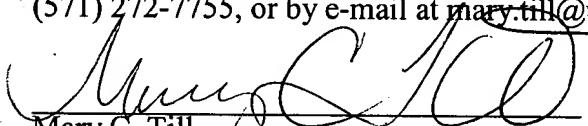
Robert T. Hrubiec, Ph.D, J.D.  
Cephalon, Inc.  
41 Moores Road  
P.O. Box 4011  
Frazer, PA 19300

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,927,855

Dear Mr. Hrubiec :

An order granting interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 4,927,855 for a period of 1 year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket #95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:  
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>  
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Inquiries regarding this communication should be directed to the undersigned by telephone at (571) 272-7755, or by e-mail at [mary.till@uspto.gov](mailto:mary.till@uspto.gov).

  
Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD-7  
5600 Fishers Lane (Rockwall II Rm 1101)  
Rockville, MD 20857

RE: NUVIGIL™ (armodafinil)  
FDA Docket No.:

Attention: Beverly Friedman

# UNITED STATES PATENT AND TRADEMARK OFFICE

In re Cephalon Inc.

Request for Interim Patent Term Extension  
U.S. Patent No. 4,927,855

: ORDER GRANTING  
: INTERIM EXTENSION

Cephalon, Inc., an agent of Laboratoire L. Lafon, the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,927,855, filed an application under 35 U.S.C. § 156 for extension of U.S. Patent No. 4,927,855 on July 26, 2007. The extended term of the patent is due to terminate on August 13, 2007, in accordance with 37 C.F.R. § 1.791. The patent claims the active ingredient armodafinil in the human drug product NUVIGIL™ and a method of use of said product which was approved by the Food and Drug Administration for commercial marketing or use on June 15, 2007. An extension of 700 days is requested.

The initial USPTO review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Because the extended term of the patent will terminate on August 13, 2007, as per 37 C.F.R. § 1.791, before a certificate of extension can be issued, interim extension of the patent term under 35 U.S.C. § 156(e)(2) is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,927,855, is granted for a period of one year from the original expiration date of the patent, i.e., until August 13, 2008.

13 Aug 2007  
Date

M. J. A. Peterlin

Margaret J. A. Peterlin  
Acting Under Secretary of Commerce for Intellectual Property  
and Acting Director of the United States Patent and Trademark  
Office